1.2 Warnings

1.1 Instructions

Instructions can cause measurement failures. It is recommended to refer to the User Manual in the relative chapter for instructions of cleaning and maintenance.

1.2.1 Do not use the finger with front on sharp materials.

1.2.2 Do not immerse the oximeter in liquid. When it needs cleaning, please wipe it with soft material, do not apply any liquid on the device directly.

1.2.3 Do not use the device with water, the temperature should be lower than 60 °C.

1.2.4 As to the fingers which are too thin or too cold, it would probably affect the normal measurement of the SpO₂ and pulse rate.

1.2.5 Do not clip the thumb for finger such as thumb and middle finger deeply enough into the probe.

1.2.6 Do not use this device on infant or newborn patients.

1.2.7 The product is suitable for children above four years old and adults (Weight should be between 15 kg to 110 kg).

1.2.8 The device may not work for all patients. If you are unable to achieve stable readings, discontinue use.

1.2.9 The display is less than 5 seconds, which is changeable according to different individual pulse rate.

1.2.10 The waveform is normalized. Please read the measured value when the waveform on screen is equable and steady-going. Here this measured value is optimal value. And do not read the measured value directly.

1.2.11 If some abnormal conditions appear on the screen during test process, pull out the finger and resume to normal state for about 10 seconds. Then try again.

1.2.12 When the parameter is particularly, this instrument does not have alarm function. Do not make any unusual observation of the SpO₂ and pulse rate when the alarms are required.

1.2.13 Batteries must be removed if the device is going to be stored for more than one month.

1.2.14 A flexible circuit joins the two parts of the device. Do not twist or pull on the central connecting line.

1.3 Principle of the Oximeter is as follows: An experience formula of data process is established through finger, and indicate the pulse intensity by the bar graph. At the same time, the device can measure the pulse rate simultaneously.

1.4.0 Principles

1.4.1 Principle of Operation

1.4.2 Features

1.4.3 Features of the operation is simple and convenient.

1.4.4 The product is small in volume. Light weight (total weight is about 45g).

1.4.5 Power consumption of the product is low (<1mA).

1.4.6 The product will enter standby mode when no signal is in the product within 5 seconds.

1.4.7 Display direction can be changed automatically to view.

1.4.8 The button can only be pressed 2 times in the same time in situations where alarms are required.

1.4.9 The SpO₂ value serves as a reference value for judgement of anaemic condition and anaemia level. Some patients with severe anaemia may also report good SpO₂ measurement.

2.1 Classification

2.1.1 The product is classified into the category II. According to the 2017 Edition of the Medical Device Management regulations.

2.1.2 The classification of device is in the product’s manual.

2.2 Features

2.2.1 The product is simple and convenient.

2.2.2 The product is small in volume. Light weight (total weight is about 45g.).

2.2.3 Power consumption of the product is low (<1mA).

2.2.4 The product will enter standby mode when no signal is in the product within 5 seconds.

2.2.5 Display direction can be changed automatically to view.

2.3.1 The product is simple and convenient.

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2.3.6 The button can only be pressed 2 times in the same time in situations where alarms are required.

2.3.7 The SpO₂ value serves as a reference value for judgement of anaemic condition and anaemia level. Some patients with severe anaemia may also report good SpO₂ measurement.

3.1.1.4 Instructions

3.1.1.4.1 The product is portable and easy to use.

3.1.1.4.2 The product is simple and convenient.

3.1.1.4.3 The product is small in volume. Light weight (total weight is about 45g.).

3.1.1.4.4 Power consumption of the product is low (<1mA).

3.1.1.4.5 The product will enter standby mode when no signal is in the product within 5 seconds.

3.2.1 Principle of Operation

3.2.2 The SpO₂ sensor and photodetector receiving tube should be arranged in a way with the subject’s finger in a position where there is no hair under the nail.

3.2.3 The SpO₂ sensor should not be used at a location or limb that are used to arterial puncture or central venous catheter insertion.

3.2.4 Make sure the optical path is free from any optical obstacles like perspex or plastic.

3.2.5 Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual-studry light, infrared, direct sunlight and etc.

3.2.6 Strumentation the use of extinguishing material is also affected by the accuracy.

3.2.7 The button can only be pressed 2 times in the same time in situations where alarms are required.

3.3.1.1.4 Instructions

3.3.1.1.4.1 The product is portable and easy to use.

3.3.1.1.4.2 The product is simple and convenient.

3.3.1.1.4.3 The product is small in volume. Light weight (total weight is about 45g.).

3.3.1.1.4.4 Power consumption of the product is low (<1mA).

3.3.1.1.4.5 The product will enter standby mode when no signal is in the product within 5 seconds.

3.3.2.1 Principle of Operation

3.3.2.2 The SpO₂ sensor and photodetector receiving tube should be arranged in a way with the subject’s finger in a position where there is no hair under the nail.

3.3.2.3 The SpO₂ sensor should not be used at a location or limb that are used to arterial puncture or central venous catheter insertion.

3.3.2.4 Make sure the optical path is free from any optical obstacles like perspex or plastic.

3.3.2.5 Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual-studry light, infrared, direct sunlight and etc.

3.3.2.6 Strumentation the use of extinguishing material is also affected by the accuracy.

3.3.2.7 The button can only be pressed 2 times in the same time in situations where alarms are required.

4.1.1.4 Instructions

4.1.1.4.1 The product is portable and easy to use.

4.1.1.4.2 The product is simple and convenient.

4.1.1.4.3 The product is small in volume. Light weight (total weight is about 45g.).

4.1.1.4.4 Power consumption of the product is low (<1mA).

4.1.1.4.5 The product will enter standby mode when no signal is in the product within 5 seconds.

4.2.1 Principle of Operation

4.2.2 The SpO₂ sensor and photodetector receiving tube should be arranged in a way with the subject’s finger in a position where there is no hair under the nail.

4.2.3 The SpO₂ sensor should not be used at a location or limb that are used to arterial puncture or central venous catheter insertion.

4.2.4 Make sure the optical path is free from any optical obstacles like perspex or plastic.

4.2.5 Excessive ambient light may affect the measuring result. It includes fluorescent lamp, dual-studry light, infrared, direct sunlight and etc.

4.2.6 Strumentation the use of extinguishing material is also affected by the accuracy.

4.2.7 The button can only be pressed 2 times in the same time in situations where alarms are required.
The device should be kept in a dry environment. Do not immerse the device in liquid. It is recommended that the device should be kept in a dry environment. Humidity may reduce the useful life of the device, or even damage it.

<table>
<thead>
<tr>
<th>Troubleshooting</th>
<th>Possible Reason</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>The SpO₂ and Pulse Rate value cannot be displayed normally</td>
<td>1. The finger is not properly positioned. 2. The patient's SpO₂ is too low to be detected.</td>
<td>1. Place the finger properly and try again. 2. Try again. Go to a hospital for a diagnosis if you are sure the device works all right.</td>
</tr>
<tr>
<td>The device cannot be turned on</td>
<td>1. The batteries are drained or almost drained. 2. The batteries are not inserted properly. 3. The malfunction of the device.</td>
<td>1. Change batteries. 2. Reinsert batteries. 3. Please contact the local service center.</td>
</tr>
<tr>
<td>The display is off suddenly</td>
<td>1. The product will enter standby mode when no signal is detected in the product within 5 seconds. 2. The batteries are almost drained.</td>
<td>1. Normal. 2. Change batteries.</td>
</tr>
</tbody>
</table>

### 10 Key of Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRbpm</td>
<td>Pulse Rate (bpm)</td>
</tr>
<tr>
<td>PSpO2</td>
<td>Pulse Oximeter Saturation(%)</td>
</tr>
<tr>
<td>LCD</td>
<td>Display Mode</td>
</tr>
<tr>
<td>LED</td>
<td>Display Mode</td>
</tr>
<tr>
<td>Pulse Rate (PR)</td>
<td>LCD</td>
</tr>
<tr>
<td>Pulse Wave</td>
<td>LCD</td>
</tr>
<tr>
<td>SpO2</td>
<td>Parameter Specification</td>
</tr>
<tr>
<td>Optical Sensor</td>
<td>Red light (wavelength is 660 nm) Infrared (wavelength is 880 nm)</td>
</tr>
<tr>
<td>Pulse Parameter Specification</td>
<td>Measuring range: 0 - 250 bpm (the resolution is 1 bpm)</td>
</tr>
<tr>
<td>Accuracy</td>
<td>±2 bpm or ±2% select range</td>
</tr>
<tr>
<td>Pulse Intensity (Pulse graph)</td>
<td>LED bar-graph display</td>
</tr>
<tr>
<td>Pulse Rate (Pulse graph)</td>
<td>LCD bar-graph display</td>
</tr>
</tbody>
</table>

### Display Information

- **The Pulse Oximeter Saturation(%)**
- **Pulse Rate (PR)**
- **Pulse Wave**
- **SpO2**
- **Optical Sensor**
- **Pulse Parameter Specification**

<table>
<thead>
<tr>
<th>Immunity test</th>
<th>IEC60601 test level</th>
<th>Compliance level</th>
<th>Electromagnetic environment-guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic discharge (ESD): IEC 61000-4-2</td>
<td>±8kV contact ±8kV air</td>
<td>±8kV contact ±8kV air</td>
<td>Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.</td>
</tr>
<tr>
<td>Power frequency (50/60Hz) magnetic field IEC 61000-4-8</td>
<td>3A/m</td>
<td>3A/m</td>
<td>Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.</td>
</tr>
</tbody>
</table>

### Dimensions and Weight

- **Dimensions**: 66(L) mm x 36(W) mm x 51(H) mm
- **Weight**: About 57 g (with the batteries)

### Additional Information

#### Guidance and manufacturer's declaration –electromagnetic emission

The CMS50D1 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the CMS50D1 Pulse Oximeter should assure that it is used in such an environment.

#### Guidance and manufacturer’s declaration –electromagnetic immunity

The CMS50D1 Pulse Oximeter is intended for use in the electromagnetic environment specified below. The customer or the CMS50D1 Pulse Oximeter should assure that it is used in such an environment.

#### Recommended separation distances between portable and mobile RF communications equipment and the CMS50D1 Pulse Oximeter

For transmitters rated at a maximum output power not listed above, the recommended separation distance (in meters) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1**: At 80MHz and 800MHz, the highest frequency range applies.

**NOTE 2**: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.